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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HA, JULIE	

ART UNIT	PAPER NUMBER
1654	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,628	BODEN ET AL.	
	Examiner	Art Unit	
	JULIE HA	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-6,11,17,19,23,24,38,41,45, 96,100 and 102-104* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1,3-7,9-12,17,19-21,23,24,36-38,41-58,61,63,69,71-73,76,81,96 and 100-104.
Continuation of Disposition of Claims: Claims withdrawn from consideration are 7,9,10,12,20,21,36,37,42-44,46-58,61,63,69,71-73,76,81 and 101.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 29, 2008 has been entered. Claims 1, 3-7, 9-12, 17, 19-21, 23-24, 36-38, 41-58, 61, 63, 69, 71-73, 76, 81, 96, 100-104 are pending in this application. Claims 7, 9-10, 12, 20-21, 36-37, 42-44, 46-58, 61, 63, 69, 71-73, 76, 81 and 101 remain withdrawn from further consideration as being drawn to nonelected invention and species. 1, 3-6, 11, 17, 19, 23-24, 38, 41, 45, 96, 100, 102-104 are examined on the merits in this office action.

Maintained Rejection

35 U.S.C. 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3-6, 11, 17, 19, 23-24, 38, 41, 45, 96, 100, 103-104 are rejected under 35 U.S.C. 102(b) as being anticipated by Aggeli et al (Peptide Science, Present and Future, 1999, 30-33) as evidenced by Biowww.net.

4. The instant claims are drawn to a material comprising ribbons, fibrils or fibres, wherein each of the ribbons, fibrils or fibres have an antiparallel arrangement of peptides in a beta-sheet tape-like substructure having a net –2 or a +2 charge when in solution at physiological pH. Furthermore, the claims are drawn to a self assembling peptide (SAP), wherein the SAP forms a tape in an aqueous medium and is made up of 3 or more polar/neutral amino acids and a plurality of charged amino acids.

5. Aggeli et al teach that the production of de novo, self-assembling, beta-sheet, tape-forming oligopeptides. These are (i) highly co-operative intermolecular hydrogen bonds, (ii) cross-strand attractive forces (hydrophobic, electrostatic, hydrogen bonding) between side-chains, (iii) tape-tape repulsive forces to prevent aggregation, (iv) lateral recognition between adjacent beta-strands to constrain their self-assembly to one-dimension, and (v) strong adhesion of solvent to the surface of the tapes to control solubility. Furthermore, the reference teaches that the produced de novo oligopeptides which self-assemble in water into polymeric, beta-sheet tapes microns in length, and at peptide concentrations above 5 mg/ml, the polymeric tapes, become entangles to produce a continuous, three-dimensional network, which transforms the initially fluid solution into a homogeneous self-supporting gel (see p. 30, 1st and 2nd paragraph in Results and Discussion). The reference further teaches an 11-mer peptide DN1-2E (QQRFEWEFEQQ) that is designed so that its self-assembly is responsive to pH. At pH values less than 4, the peptide molecules self-assemble into stable beta-sheet structures and form gel (see p. 30, 3rd paragraph in Results and Discussion and Figure 1). This peptide has the same sequence as P11-3. The peptide is made up of 3 or more

polar/neutral amino acids and a plurality of charged amino acids, has glutamine, glutamic acid, form a gel at a pH of less than at neutral pH, at least 50% of the amino acids comprise an alternating structure of polar and apolar amino acids, forms a tape in an aqueous medium, has phenylalanine and tryptophan residues. The reference teaches 260 μM of peptide concentration in phosphate buffer. This implies that 1554 g/mol x 260 μM = .404 g/l of the peptide. Thus, this meets the limitation of claims 1, 3-6, 11, 17, 19, 23-24, 38, 41, 45, 96, 100, 103. Furthermore, the reference discloses that it is interesting to compare the properties of these self-assembling peptide gels with the more classical biopolymer gels such as gelatin and agarose. The elastic and dissipative moduli are very similar. The stress response to strain for a peptide gel remains linear up to 230% strain, compared to conventional biopolymer gels which typically break at strains of 50%. The gels also show high thermal and chemical stability, and tare both biodegradable and biocompatible, and are found to be stable in the presence of a variety of solutes, including biological proteins. Furthermore, the reference discloses that this combination of properties of the polymeric peptide tapes, coupled with the ability to engineer functionality into the polymer by peptide design, make these materials attractive for the development of a wide range of applications. Switching between gel and fluid states may be used for drug delivery, where the drug molecule encapsulated in the polymeric gel network is released in response to a switch in pH (see p. 32, 2nd and 3rd paragraphs). Furthermore, the peptide DN1-2E having the same peptide sequence as claimed would have inherent properties and functionalities as P11-3. Thus, this meets the limitations of claims 1, 3-6, 11, 17, 19, 23-24, 38, 41, 45, 96, 100, 103-104.

The reference teaches a phosphate buffer. As evidenced by biowww.net/buffer-reagent/1x-Phosphate-Buffered-Saline.html, it states that 8g of NaCl is added to 1 L of water. NaCl has a molecular weight of 56.44 g/mol. When 8g is divided by 56.44 g/mol and 1 L of water, it comes out to about 142 mM. This is about 145 mM, thus meets the limitation of claim 104. It is noted that claims 103-104 have been rejected over the prior art, even though the reference does not disclose exact pH or NaCl concentration as claimed. However, the claims utilize the term "about" when discussing the pH and NaCl concentration. The term "about" allows for some tolerance in the ranges disclosed. In *In re Ayers*, the Federal Circuit held that "at least about 10%" was anticipated by a reference that disclosed "about 8%" because the term "about" allowed for some tolerance. In re Ayers, 154 F.2d 182, 185 (Fed. Cir. 1946). Similarly, in Johnson and Johnson v. W.L. Gore & Associates, Inc., the Court allowed for "about 1.2" to be inclusive of 1.0. See Johnson and Johnson v. W.L. Gore & Associates, Inc., 436 F.Supp. 704, 728-729 (Fed. Cir. 1977). Although about has never been confined to specific percentage of variability, the Johnson and Johnson decision at least implies that 16% variability is permissible when "about" is used (1.0/1.2 = ~16.6% variability). Thus, the term "about" implicitly discloses some variability even though the specification may not literally cite this variability. Thus, the disclosure of a pH of 7 encompasses a pH of "about" 7.5; the disclosure of 142 mM of NaCl encompasses a NaCl concentration of about 145 mM, as claimed.

Please note that claim 1 has been only examined to the elected invention of peptide P11-3.

Response to Applicant's Arguments

6. Applicant argues that "claim 1 is directed to a material comprising ribbons, fibrils or fibres wherein each of the ribbons, fibrils or fibres has an antiparallel arrangement of peptides in a b-sheet tape-like substructure at physiological pH and physiological salt concentrations, wherein each peptide comprises a net -2 or a +2 charge, and wherein the peptide is P11-3." Applicant argues that "in contrast to the pending claims, Aggeli et al teach that a peptide having the amino acid sequence of P11-3 when in water is only capable of forming a β-sheet tape-like structure at pH 4 or less...Aggeli et al teach that this peptide when in water is a fluid at physiologic pH. Thus, in Aggeli et al, the peptide was exposed to water, not to physiological pH and salt conditions. The phosphate buffer referenced on pages 5-7 of the Office action and in Figure 3 of Aggeli et al does not provide physiological salt concentrations. There is no NaCl present. The phosphate buffer has sodium phosphate but not sodium chloride."

7. Applicant's arguments have been fully considered but have not been found persuasive because of the following reasons.

Aggeli et al reference teaches the same peptide sequence (DN1-2E) as the instant P11-3 sequence. The reference further teaches that DN1-2E self-assemble into stable β-sheet structure and forms a gel at pH 2 and β-sheet structure at pH 7. The fact that the peptides are in fluid at pH 7 has no bearing on whether the peptide is formed as fibril or not. The peptide solution can be opaque in color and still have the peptide formed as fibril. Additionally, the peptide does not become a fluid. The peptide can be in a fluid solution, but on a molecular level, the peptide remains a solid. As described in

the rejection above, the peptide DN1-2E having the same peptide sequence as claimed would have inherent properties and functionalities as P11-3. Thus, polymer of DN1-2E would inherently form the material at physiological pH and physiological salt concentration as claimed. Furthermore, Aggeli reference teaches that at pH 7, it forms an unstable β-sheet. The claims do not recite whether the β-sheets are in the gel form or in the fluid form. Instant claim 1 recites, "A material comprising ribbons, fibrils, or fibres, wherein each of the ribbons, fibrils or fibres has an antiparallel arrangement of peptides in a b-sheet tape-lie substructure at physiological pH and physiological salt concentrations, wherein each peptide comprises a net -2 or a +2 charge, wherein the peptides is P11-3." The Aggeli reference teaches that at pH 7, the DN1-2E (same peptide sequence as P11-3) has an unstable β-sheet structure. Aggeli reference teaches a β-sheet structure at pH 7 (whether it is stable or not, it is still a β-sheet structure, as claimed). As described above, a phosphate buffered saline would have a physiological salt concentration. Therefore, Aggeli et al reference meets all of the limitations of the instant claims.

Furthermore, the MPEP states the following: "The discovery of a new use for an old structure based on unknown properties of the structure might be patentable to the discoverer as a process of using. However, when the claim recites using an old composition or structure and is directed to a result or property of that composition or structure, then the claim is anticipated. See MPEP 2105. Since the claims are drawn to a material comprising the P11-3 peptide, the Aggeli et al reference anticipates the instant invention.

Furthermore, Aggeli reference does not indicate that the peptide is in water only. The Examiner could not find that the DN1-2E β-sheet dimers (see Figure 1) was in water only. Further, a phosphate buffer of Aggeli reference does not indicate that it only has sodium phosphate. A phosphate buffer can be made from different recipes, as the one cited in the body of the rejection above (i.e. phosphate buffered saline). As evidenced by the instant specification, "the rationally designed peptide P11-3 (Table 1) was dissolved in 145 mM NaCl, pH about 7.5 aq. Solution (I.e. the ionic strength and pH values of the solution were similar to those present in cell culture medium)or it was directly in cell culture medium" (see paragraph [0101] of instant specification 2006/0154852 A1). It is well known in the art that phosphate buffered saline is utilized in cell culture medium. Furthermore, the claim recites a material comprising ribbons, fibrils or fibres wherein each of the Ribbons, fibrils or fibres has an antiparallel arrangement of peptides in a b-sheet tape-like substructure…wherein the peptide is P11-3. Since Aggeli reference teaches the same peptide sequence as the claimed P11-3, it would inherently from the β-sheet tape like structure at physiological pH and physiological salt concentrations.

First, it should be noted that the claims of the instant a material comprising ribbons, fibrils or fibers, wherein each of the ribbons, fibrils or fibers has an antiparallel arrangement in a beta-sheet tape like structure at physiological pH and physiological salt concentrations wherein the peptide is P11-3. It unquestionable that the prior art teaches the same peptide at the same pH and salt concentration as claimed in the instant application. Yet Applicants are arguing that their composition forms fibrils and

the prior art peptide does not. It begs the question, given that it is the same peptide at the same pH and salt concentration, are the claims are omitting some criticality that results in this distinction? In essence how did Applicants material form fibrils and the prior art did not, when the same peptide and same pH and salt concentration are at issue? However, Applicants have not proven that the prior at product does not form fibrils, as argued above, and thus such a question might be too early for inquiry. Furthermore, Applicant is reminded that the claims are drawn to a material comprising peptide P11-3. The claims are not drawn to a method of making the material comprising peptide P11-3, nor a product by process. Therefore, a material comprising the same peptide sequence as the instant peptide P11-3 would inherently have all functionality and characteristics as the claimed material comprising P11-3. In other words, the peptide would inherently have the structure of instant claims at physiological pH and physiological salt concentration.

Furthermore, the product of the claim 1 is defined in terms of a laboratory designation rather than by physical characteristics, structure or even the process by which the product is prepared. Consequently, comparison of this product with the prior art is difficult since the Office is not equipped to manufacture the claimed product and/or prior art products that appear to be related and conduct comparisons. Thus a lesser burden of proof is required to make out a case of anticipation for a product claimed in terms of a laboratory designation than when claimed in conventional fashion by its physical characteristics, structure or even in terms of the process by which it is made.

Therefore, it is the Examiner's position that Aggeli et al have produced a material which comprise ribbons, fibrils or fibres, wherein each of the ribbons, fibrils or fibres has an antiparallel arrangement of peptides in a β-sheet tape-like substructure at physiological pH and physiological salt concentrations, wherein peptide is P11-3. One of ordinary skill in the art would reasonably conclude that Aggeli's material comprising the same peptide as P11-3 also possesses the same structural and functional properties as those of the material claimed and, therefore, it appears that Aggeli et al have produced materials comprising ribbons, fibrils or fibres that are identical to the claimed materials. Since the Patent and Trademark Office does not have the facilities for examining and comparing the claimed material comprising ribbons, fibrils or fibres with the materials of Aggeli, the burden of proof is upon the Applicants to show an unobvious distinction between the structural and functional characteristics of the claimed hybridoma and antibody and the hybridoma and antibody of the prior art. See *In re Best*, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

New Objection

8. Claims 1, 3-6, 11, 17, 19, 23-24, 38, 41, 45, 96, 102-104 are objected for reciting nonelected invention in the claims. Applicant is advised to cancel all claims drawn tononelected inventions.

This application contains claims drawn to an invention nonelected with traverse in the reply filed on May 29, 2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

New Rejection

35 U.S.C. 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1, 3-6, 11, 17, 19, 23-24, 38, 41, 100 and 103 are rejected under 35 U.S.C. 102(a) as being anticipated by Agelli et al (WO 2003/006494, filed with IDS).

11. Agelli teaches the peptide sequence QQRFEWEFEQQ (DN1-2E, see Example 1), that is the same as the instant peptide sequence P11-3. Agelli further teaches that certain beta-sheet tape forming peptides can also give rise to beta barrels (see p. 2, lines 15-20). The reference teaches that the material comprise discrete peptide molecule each adopting beta stand conformation (see p. 2, lines 22-24). The reference teaches that the experimental conditions were pH 7-8, 450 mM KCl and 150 mM KCl,

which meets the limitation of physiological pH and physiological salt concentrations (see p. 7, line 17). The reference further teaches a wound dressing comprising fibrils or fibres comprise two or more tapes twisted together characterized in that fibrils or fibres have polypeptide beta barrel holes interspersed in them (see claim 12). Since the reference teaches the peptide DN1-2E, which is the same as the instant peptide P11-3, it would inherently have the same functionality and characteristic as the instantly claimed material. Therefore, the peptide would inherently form a beta-sheet tape like structure at physiological pH and physiological salt concentrations. Therefore, the reference anticipates instant claims 1, 3-6, 11, 17, 19, 23-24, 38, 41, 100 and 103.

12. Claims 1, 3-6, 11, 17, 19, 23-24, 38, 41, 100 and 103 are rejected under 35 U.S.C. 102(e) as being anticipated by Agelli et al (WO 2003/006494, filed with IDS).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

13. Agelli teaches the peptide sequence QQRFEWEFEQQ (DN1-2E, see Example 1), that is the same as the instant peptide sequence P11-3. Agelli further teaches that certain beta-sheet tape forming peptides can also give rise to beta barrels (see p. 2, lines 15-19). The reference teaches that the material comprise discrete peptide

molecule each adopting beta stand conformation (see p. 2, lines 22-24). The reference teaches that the experimental conditions were pH 7-8, 450 mM KCl and 150 mM KCl, which meets the limitation of physiological pH and physiological salt concentrations (see p. 7, line 17). The reference further teaches a wound dressing comprising fibrils or fibres comprise two or more tapes twisted together characterized in that fibrils or fibres have polypeptide beta barrel holes interspersed in them (see claim 12). Since the reference teaches the peptide DN1-2E, which is the same as the instant peptide P11-3, it would inherently have the same functionality and characteristic as the instantly claimed material. Therefore, the peptide would inherently form a beta-sheet tape like structure at physiological pH and physiological salt concentrations. Therefore, the reference anticipates instant claims 1, 3-6, 11, 17, 19, 23-24, 38, 41, 100 and 103.

35 U.S.C. 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 1, 3-6, 11, 17, 19, 23-24, 38, 41, 45, 96, 100, 103-104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aggeli et al (Peptide Science, Present and Future, 1999, 30-33) as evidenced by Biowww.net.

18. The teachings of Aggeli et al are described, supra. The difference between the reference and the instant claim is that the reference does not teach a peptide concentration of greater than 15 mg/ml.

19. However, it would have been obvious to one of ordinary skill in the art to optimize the peptide concentration to produce the best material comprising ribbons, fibrils or fibres. The Aggeli reference teaches 0.404 g/L peptide concentration. The MPEP states the following: Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. *"[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ*

233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("*The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.*"); *In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969)* (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). An artisan would try to use the optimal peptide concentration from a finite number of predictable solutions to achieve a material comprising the optimal β-sheet ribbons, fibrils or fibres. In other words, it would be obvious to choose from a finite number of predictable solutions if peptide is one of the components.

Therefore, the optimization of the peptide concentration through routine **optimization** is deemed merely a matter of judicious selection and routine optimization that is well within the purview of skilled artisan.

Conclusion

20. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE HA whose telephone number is (571)272-5982. The examiner can normally be reached on Mon-Thurs, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cecilia Tsang/
Supervisory Patent Examiner, Art Unit 1654

/J. H./
Examiner, Art Unit 1654